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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,867	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 26-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2006 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 18, 2006 has been acknowledged and is being considered by the Examiner.

Claim Objections

3. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires that the implantable medical device "comprise a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings; and an overmold that at least partially encapsulates each of the housings, where the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold". The Examiner interprets this limitation to mean that

the overmold completely encapsulates each of the modules because of the phrase "separately encapsulated".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear to the Examiner what exactly is being defined in Claim 12, since the limitations appear to be contradictory to the limitations previously set forth in Claim 1. For instance, Claim 1 requires that the implantable medical device "comprise a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings; and an overmold that at least partially encapsulates each of the housings, where the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold". The Examiner interprets this limitation to mean that the overmold completely encapsulates each of the modules because of the phrase "separately encapsulated". Claim 12, however, contradictorily defines an overmold, which "does not encapsulate a portion of each of the modules that is proximate to a cranium of a patient".

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 6, 9, 12-13, 18, 21, 23, 26 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with, proximate to or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The Examiner makes exemplary suggestions for revision below.

The Examiner suggests changing the last three lines of Claim 1 to be similar to "wherein the overmold is preformed to be concave, prior to manipulation of the implantable medical device, such that a surface of the overmold is adapted to be proximate a cranium of a patient". Similar changes should also be applied to Claim 30.

The Examiner suggests rewording Claim 6 to read, "wherein the surface of the overmold is concave such that the surface is adapted to conform substantially to the cranium".

The Examiner suggests rewording Claim 9 to be similar to "wherein the implantable medical device is adapted to be implanted on the cranium and wherein the overmold comprises a first surface and a second surface, wherein the second surface of the overmold is adapted to be distal from the cranium."

8. As stated above, these are only examples and the Examiner respectfully requests that the Applicant revisit and revise the claims to overcome the 35 U.S.C. 101 against them.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6, 10-11, 13, 18-19 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Leysieffer et al. (U.S. 6,131,581) (herein Leysieffer). As to Claims 1, 6 and 11, Leysieffer discloses an implantable thermoelectric energy converter, read as an implantable medical device 10 comprising a plurality of interconnected modules 20, each of the modules comprising a respective one of a plurality of housings and a thermally insulating composite element, read as an overmold 23 that at least partially encapsulates each of the housings of the interconnected modules 20 (see Leysieffer Abstract, Figs. 1-4, column 1, lines 65-67, column 2, lines 1-24 and lines 51-67, column 4, lines 4-21 and column 5, lines 1-22). The Examiner makes specific reference to Leysieffer Figs. 5 and 6, where the interconnected modules 20 are shown as being "horizontally distributed at respective locations of the overmold 23" in a liner configuration. Leysieffer specifies at column 5, lines 1-4 that the housings of the modules 20 are separately encapsulated by the overmold 23 (see Leysieffer Figs. 5 and 6 and column 5, lines 1-4). Leysieffer further specifies that the overmold 23 is formed such that a surface of the overmold 23 that is proximate to a skull, read as a cranium 14 of a patient when the implantable medical device 10 is implanted on the cranium 14, is built to be arched or dome-shaped, read as concave along at least one axis. Leysieffer specifies that this be done so that the implantable medical device 10 "optimally corresponds to the arched surface of the skull" (see Leysieffer Figs. 3-4 and column 5, lines 47-62).

11. As to Claim 2, it is inherent that a device that is "arched" or "shaped in a dome" is concave along two axes (see Leysieffer Figs. 3-4 and column 5, lines 47-62).

12. As to Claims 3 and 4, Leysieffer discloses that the overmold 23 is flexible and may comprise silicone (see Leysieffer column 5, lines 4-17).

13. As to Claim 5, Leysieffer discloses that material of the overmold 23 may be selected from the group consisting of polytetrafluorethylene, polycarbonates, polyurethane, silicones, and carbon fiber-reinforced polymers (see Leysieffer column 5, lines 4-17). It is inherent that these materials comprise at least two materials.

14. As to Claim 10, the Examiner makes specific reference to Leysieffer Figs. 5 and 6, where the interconnected modules 20 are shown as being "horizontally distributed at respective locations of the overmold 23" in a liner configuration (see Leysieffer Figs. 5 and 6).

15. As to Claims 13 and 18, the Examiner makes specific reference to Leysieffer Fig. 3, where it appears that the housings of each of the modules comprises a surface that is proximate to a cranium 14 when the implantable medical device 10 is implanted on the cranium and the surface of the housing of at least one of the modules is concave along at least one axis such that the surface conforms substantially to the cranium 13 (see Leysieffer Fig. 3).

16. As to Claims 28 and 29, Leysieffer discloses that the housings of the modules 20 may comprise metals such as titanium and titanium alloys (see Leysieffer column 4, lines 26-41). It is inherent that the housings of the modules are hermetic, otherwise the semiconductor properties of the modules or the energy generation properties would be compromised.

17. Claims 14 and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Leysieffer. Leysieffer discloses an alternate embodiment where the energy converter 10, the energy storage 27, the control unit 28 and the active implant 26, such as a stimulus generator are integrated in a single implant 35 (see

Leysieffer Fig. 9, column 6, lines 64-67 and column 7, lines 1-19). It is inherent or at least obvious to one having ordinary skill in the at that the this embodiment (the overmold 23 and gthe individual modules) would also be shaped in a dome (i.e. concave along two axes) since Leysieffer teaches that this is desirable of implants located at the mastoid region 11 of the cranium 14 (see Leysieffer column 5, lines 48-62).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 7-9, 19-21 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer. As to Claims 7, 19 and 30-31, Leysieffer discloses the claimed invention as discussed above, except it is not specified that the arc or dome shape of the overmold 23 has a radius within a range from 4.5 to 9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radius within a range from 4.5 to 9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

20. As to Claims 8 and 20, Leysieffer discloses the claimed invention as discussed above, except it is not specified that the arc or dome shape of the overmold 23 has a radius equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to make the radius 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

21. As to Claim 9, it is apparent upon inspection of Leysieffer Fig. 3 that the overmold 23 comprises two surfaces, with a second surface being distal from the cranium 14. Leysieffer further specifies that the overmold 23 is formed such that a surface of the overmold 23 that is proximate to a skull, read as a cranium 14 of a patient when the implantable medical device 10 is implanted on the cranium 14, is built to be arched or dome-shaped, read as concave along at least one axis. Leysieffer specifies that this be done so that the implantable medical device 10 "optimally corresponds to the arched surface of the skull" (see Leysieffer Figs. 3-4 and column 5, lines 47-62).

22. As to Claim 21, the Examiner makes specific reference to Leysieffer Fig. 3, where it appears that the housings of each of the modules comprises a surface that is proximate to a cranium 14 when the implantable medical device 10 is implanted on the cranium and the surface of the housing of at least one of the modules is concave along at least one axis such that the surface conforms substantially to the cranium 13 (see Leysieffer Fig. 3).

23. Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto (U.S. 4,094,321). As to Claims 23 and 26, Muto discloses an implantable pacemaker, read as an implantable medical device 30 comprising a metallic housing 42 (see Muto Fig. 1 and column 2, lines 53-56). The Examiner takes the position that any surface of the housing 42 of the implantable medical device 30 is capable of being proximate to a cranium of a patient, where "proximate" means "near", since the pacemaker is typically implanted in the chest region of a body. The chest of a patient is "near" a cranium of a patient. Muto specifies that the

implantable medical device 30 is "of generally domical configuration" such that the surface conforms substantially to an arc (see Muto Fig. 1 and column 2, lines 47-53). It is inherent that a device that is "arched" or "shaped in a dome" is concave along two axes.

Muto discloses the claimed invention as discussed above, except it is not specified that the arc or dome shape has a radius within a range from 4.5 to 9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radius within a range from 4.5 to 9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

24. As to Claim 24, discloses the claimed invention as discussed above, except it is not specified that the arc or dome shape has a radius equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radius 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

25. As to Claim 27, Muto discloses that the device 30 comprises a therapy delivery circuit to deliver stimulation and control electronics 32 to control the delivery of the stimulation and that both elements are located within the housing of the device 30 (see Muto Fig. 5, column 1, lines 41-49 and column 2, lines 35-64). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant

case, the pacemaker 30 of Muto is capable of stimulating the brain along with any other part of the body.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 22-37, 3940, 42-53 and 55 (Amended on November 28, 2005) of copending Application No. 10/731,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 15-17 and 22-23 (Amended May 24, 2006) of copending Application No. 10/731,868. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 (Amended November 16, 2005) of copending Application No. 10/731,638. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

30. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 (Amended June 16, 2006) of copending Application No. 10/730,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

31. Applicant's arguments with respect to claims 1-24 and 26-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Engmark et al. (U.S. 2004/0082977) discloses a concave implantable medical device comprising interconnected horizontally distributed modules.

Ives et al. (U.S. 6,266,556) teaches that it is desirable for devices placed near a cranium to be "cup" shaped.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel 08/02/06
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Art Unit 3766

Robert E. Pezzuto
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